AUTOMATIC LIQUID PACKAGING, INC.

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
http://www.alp-bfs.com

July 20, 1999

Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Extra Eye Drops

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contact manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 – 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349.** The line consists of the following:

PRODUCT NAME	ACTIVE INGREDIENT
Extra Eye Drops	Tetrahydrozoline HCL (a vasoconstrictor) Polyethylene Glycol 400 (a demulcent)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in **21 CFR 349**.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "**Over-The-Counter Human Drugs; Labeling Requirements"** for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel. In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop

Container opening instructions Statements such as this also must appear on the outside package.

As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will aquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

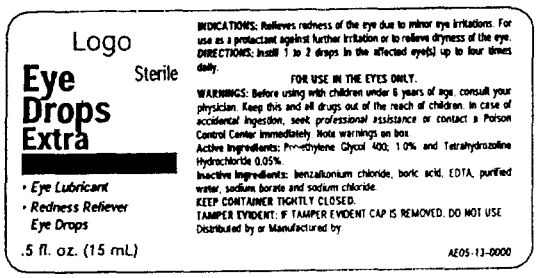
Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.

John Brda
Regulatory Affairs Manager

c Al Rothchild

.5 Oz. Extra Eye Drops



Logo

Eye Drops Extra Sterile

- *Eye Lubricant*
- *Redness Reliever Eye Drops*

.5 fl. oz. (15 mL)

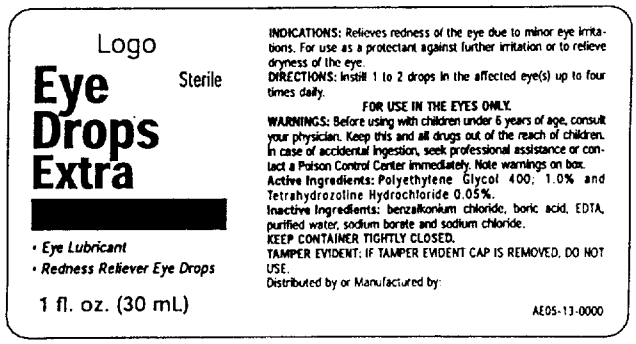
INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.
Active Ingredients: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.
Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.
KEEP CONTAINER TIGHTLY CLOSED.
TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.
Distributed by or Manufactured by

AE05-13-0000

1 Oz. Extra Eye Drops



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Eye Drops Extra

Sterile

[redacted]

- *Eye Lubricant*
- *Redness Reliever Eye Drops*

1 fl. oz. (30 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

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Distributed by or Manufactured by:

AE05-13-0000

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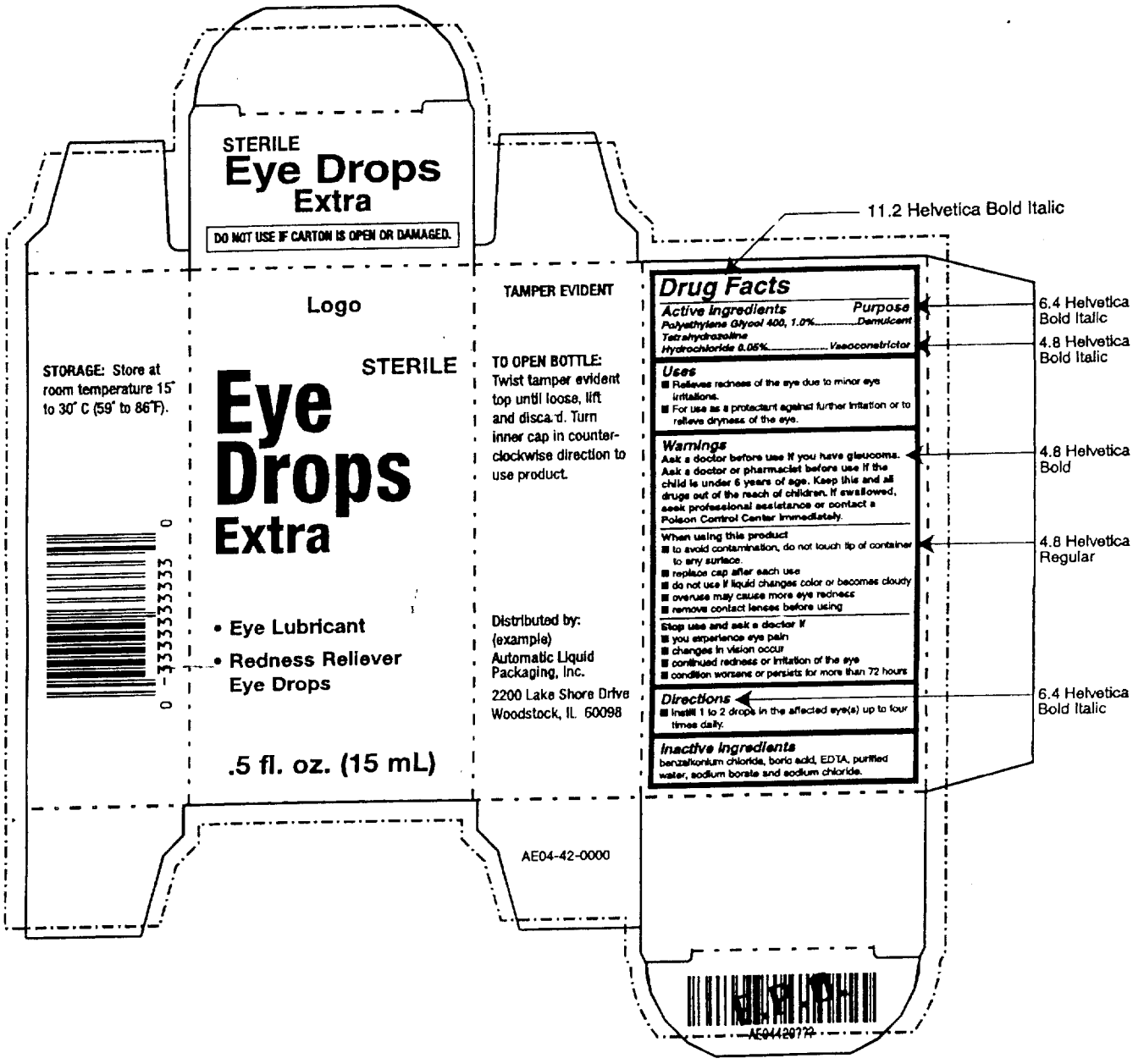

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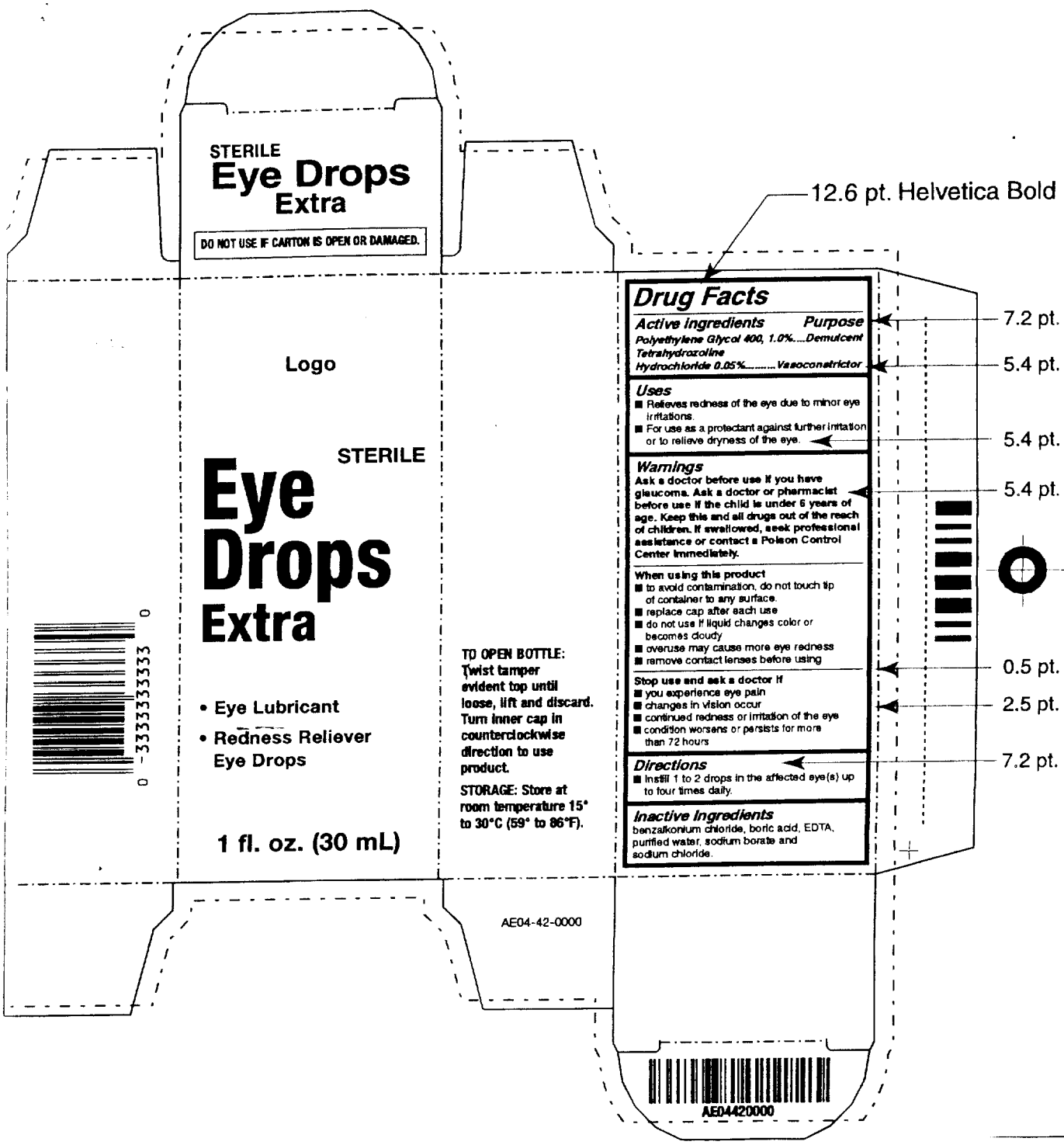

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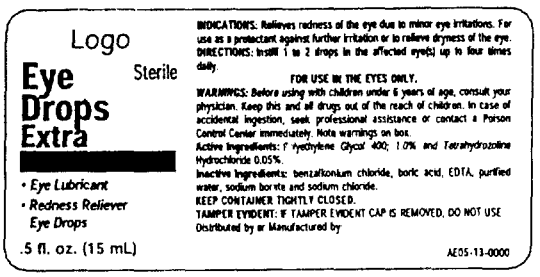
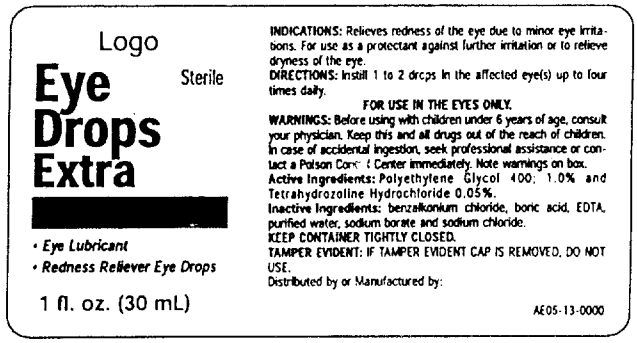


1 Oz. Extra Eye Drops



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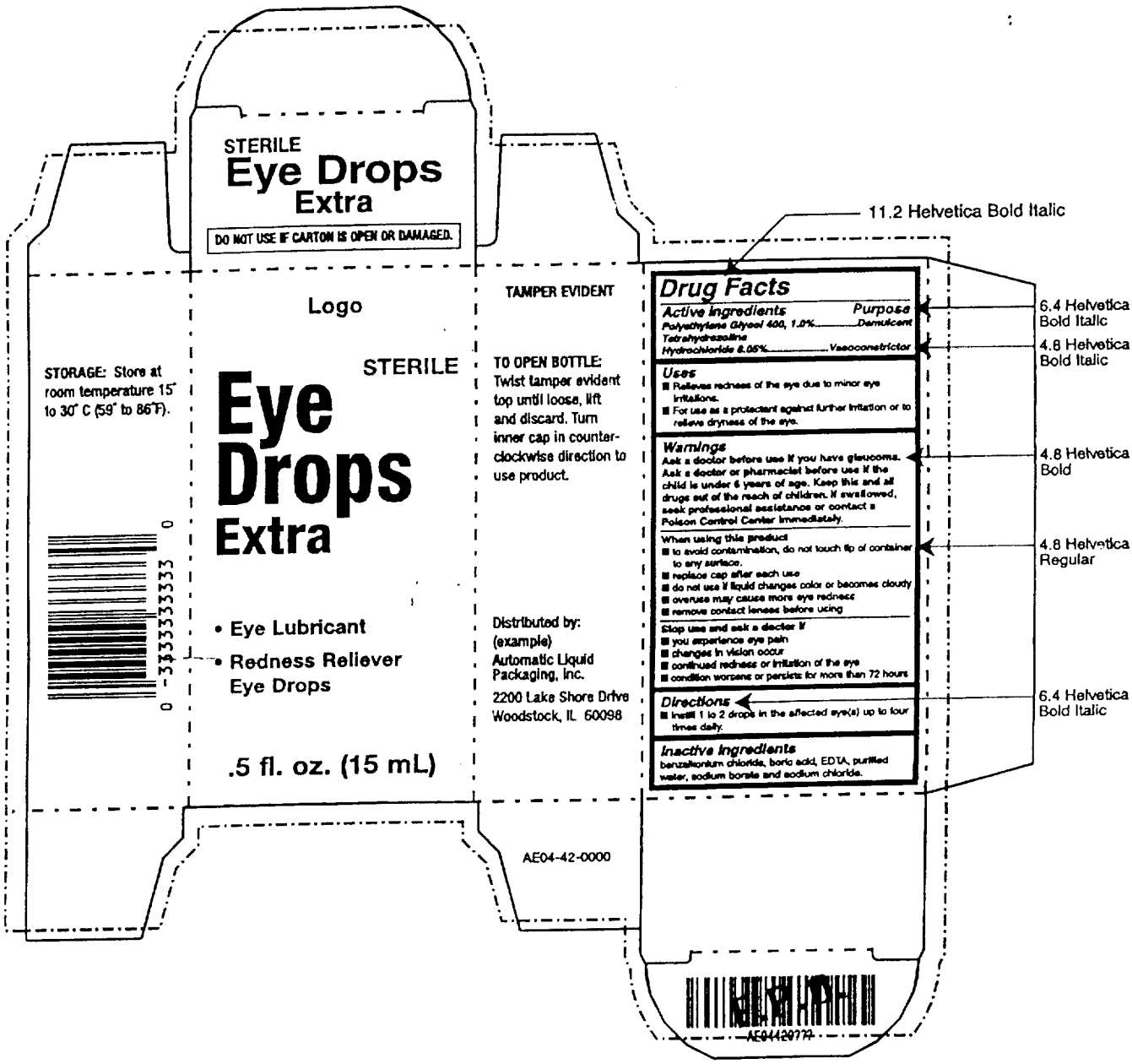

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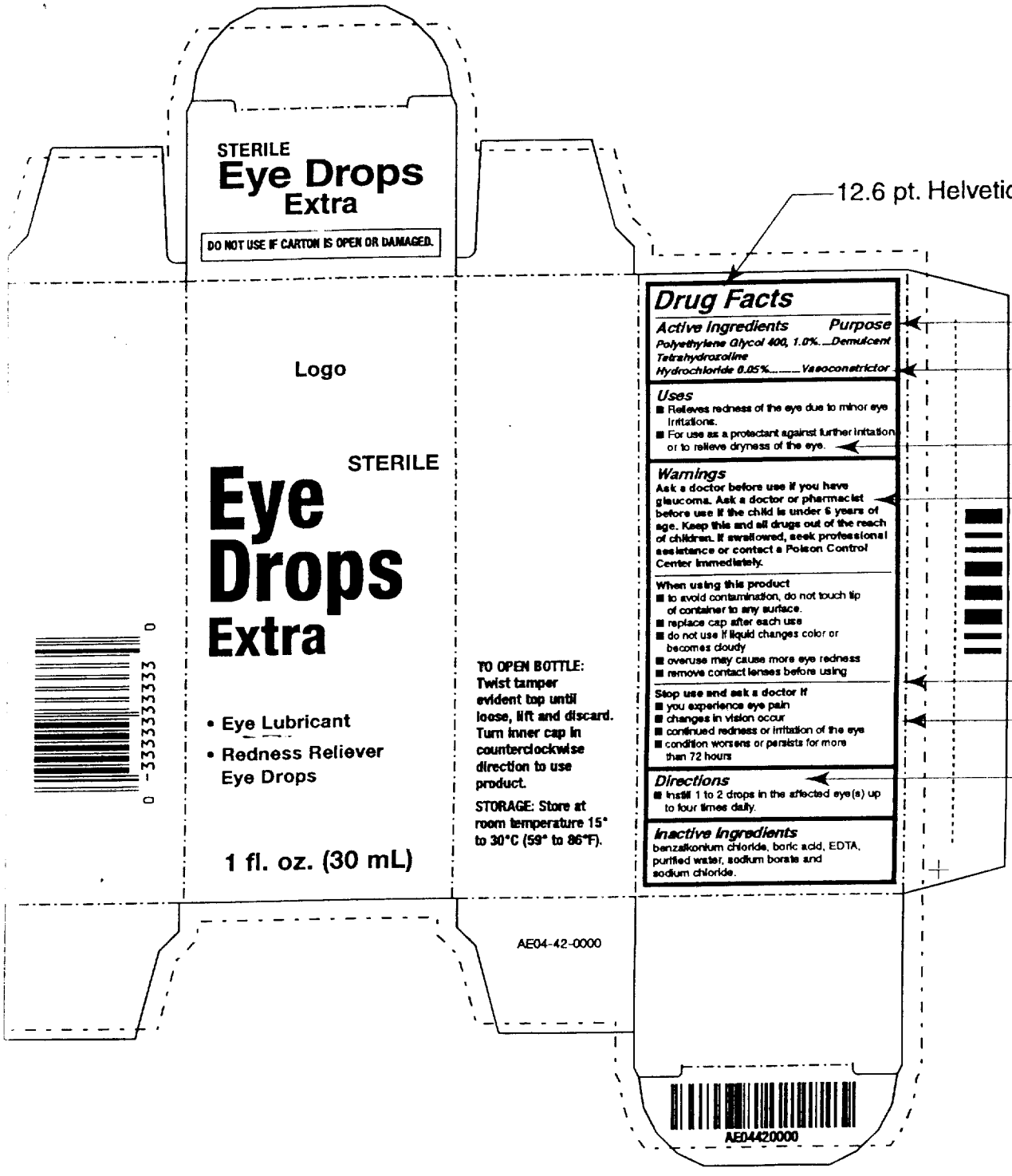

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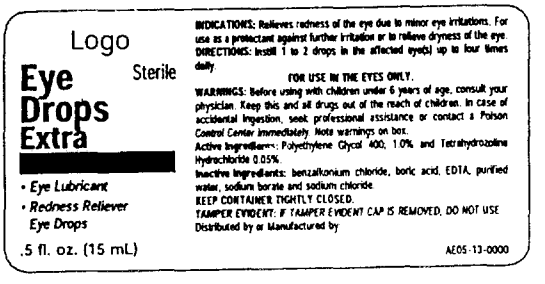

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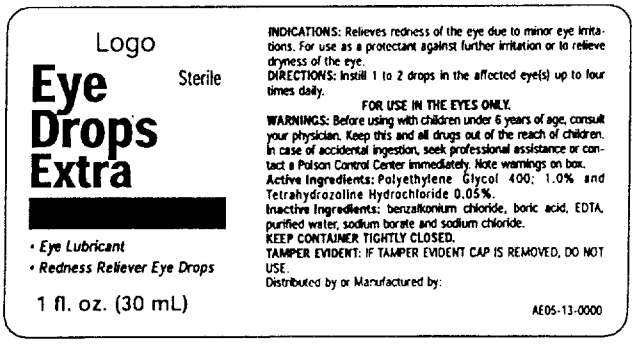

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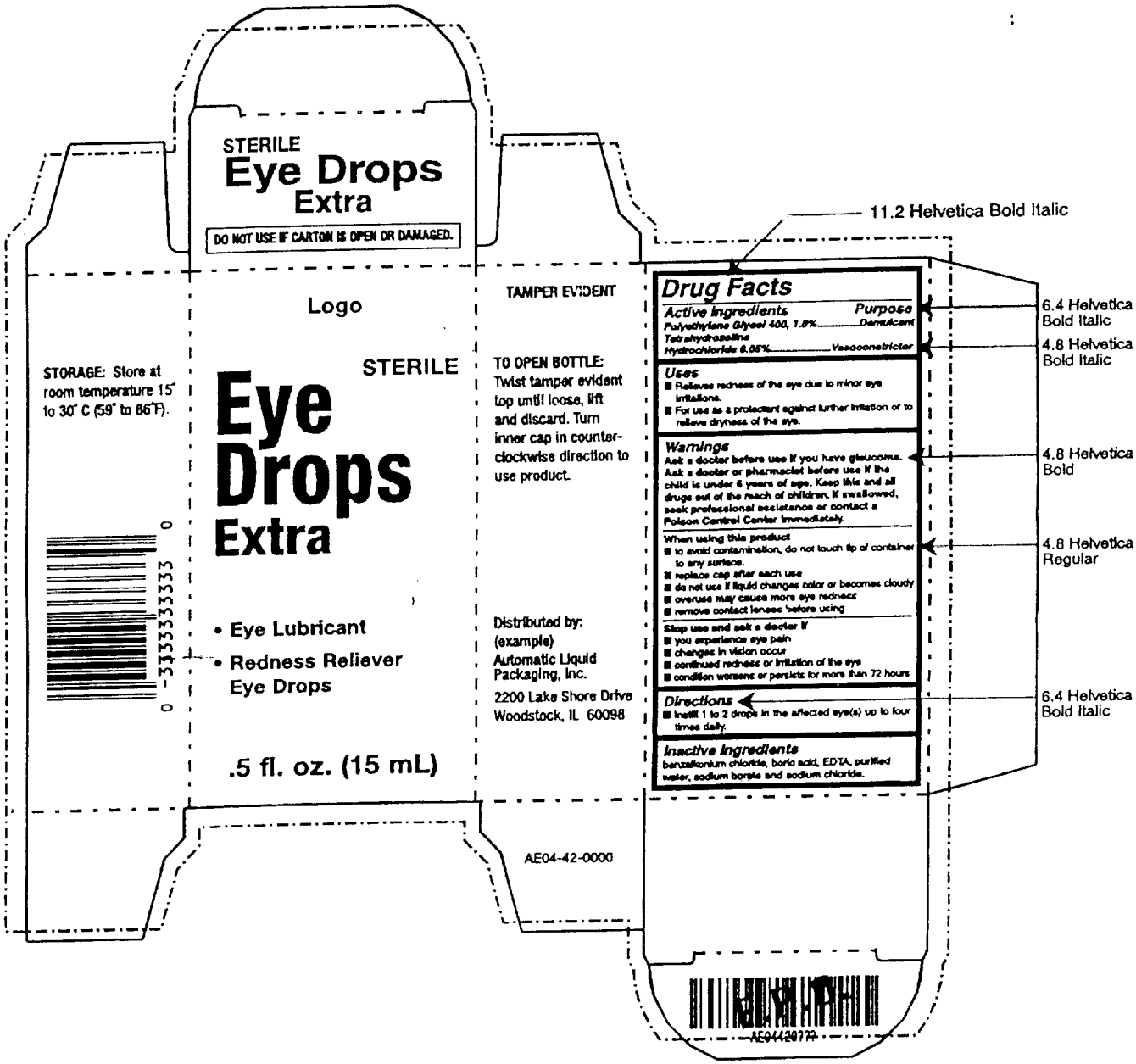

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